timeframe for maintaining such records. FDA agrees that a reasonable timeframe should be established for maintaining such records and intends to specify such timeframes as part of the approval order. Accordingly, FDA has modified the regulation to state that records shall be maintained in accordance with the approval order for the HDE.

Section 814.124(a) is amended to allow physicians in emergency situations to administer a HUD prior to obtaining institutional review board (IRB) approval. In such situations, the physician is required to provide written notification, including the identification of the patient involved, the date of use, and the reason for use, to the IRB within 5 days after emergency use. FDA anticipates that five physicians will use HUD's in emergency situations before obtaining approval from an IRB. FDA estimates that notifications under this section will take an average of 1 hour per response.

In addition to the changes required by FDAMA, FDA is amending § 814.104(b)(5) to allow a sponsor who is charging more than $250 per HUD to submit, in lieu of a report by an independent CPA, an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the device's cost of research, development, fabrication, and distribution. In addition, the amendments to § 814.104(b)(5) waive the requirement for submission of any CPA report or attestation for HUD's for which an HDE applicant is charging $250 or less. FDA anticipates, based on past experience, that 7 of the anticipated 15 HDE holders per year will charge less than $250 per HUD, and thus be exempt from the § 814.104(b)(5) requirement altogether. For the remaining eight HDE holders, FDA anticipates that all will submit attestations in lieu of CPA reports, and estimates that these submissions will require 2 hours to complete.

Description of Respondents: Business or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.104(b)(5)	8	1	8	2	16
814.124(a)	5	1	5	1	5
814.126(b)(1)	15	1	15	120	1,800
Total					1,821

[1] There are no operating and maintenance costs or capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	15	1	15	2	30

[1] There are no operating and maintenance costs or capital costs associated with this collection of information.

Dated: July 31, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-21088 Filed 8-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0290]

Determination of Regulatory Review Period for Purposes of Patent Extension; Aqueous Aryl Fluorophosphite Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Aqueous Aryl Fluorophosphite Suspension and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may

have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the food additive Aqueous Aryl Fluorophosphite Suspension (2,2'-ethylidenebis(4,6-di-tertbutylphenyl)fluorophosphonite). Aqueous Aryl Fluorophosphite Suspension is used as an antioxidant used in adhesives and in the preparation of polymers intended for contact with food. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aqueous Aryl Fluorophosphite Suspension (U.S. Patent No. 4,912,155) from Albemarle Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 1998, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of Aqueous Aryl Fluorophosphite Suspension represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Aqueous Aryl Fluorophosphite Suspension is 2,930 days. Of this time, 935 days occurred during the testing phase of the regulatory review period, 1,995 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test ("test") involving this food additive product was begun*: January 9, 1989. The applicant claims July 21, 1986, as the date the test was begun. However, FDA records indicate that the test was begun on January 9, 1989.

2. *The date the petition requesting the issuance of a regulation for use of the additive ("petition") was initially submitted with respect to the food additive product under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348)*: August 1, 1991. FDA has verified the applicant's claim that the petition was initially submitted on August 1, 1991.

3. *The date the petition became effective*: January 15, 1997. FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on January 15, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,390 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 6, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 3, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–21130 Filed 8–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0220]

Determination That Acyclovir 200-Milligram Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that acyclovir 200-milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for acyclovir 200-mg tablets.

FOR FURTHER INFORMATION CONTACT: Richard L. Schwartzbard, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," a publication generally known as the "Orange Book." Under the FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated September 17, 1997 (Docket No. 98P–0220/CP1), received by FDA on April 1, 1998, and submitted in accordance with 21 CFR 314.122, TorPharm Inc., requested that the agency determine whether acyclovir 200-mg tablets were withdrawn from sale for reasons of safety or effectiveness. Acyclovir 200-mg tablets are the subject of approved ANDA 74–